5.0 STANDARDIZED PACKAGING AND TRANSPORTING OF ORGANS AND TISSUE TYPING MATERIALS

The following policies address standardized packaging of live and deceased donor organs and tissue typing materials to be transported for the purposes of organ transplantation. When a deceased donor organ is procured, the Host OPO shall be responsible for ensuring the accuracy of the donor's ABO on the container label and within the donor's documentation. Each OPO shall establish and implement a procedure for obtaining verification of donor ABO data by an individual other than the person initially performing the labeling and documentation requirements put forth in policy 5.2 and 5.3. The OPO shall maintain documentation that such separate verification has taken place and make such documentation available for audit.

Upon receipt of a live or deceased donor organ and prior to implantation, the Transplant Center shall be responsible for determining the accuracy and compatibility of the donor and recipient ABO and document this verification in compliance with Policy 3.1.2.

5.1 SPECIMEN COLLECTION AND STORAGE. Each OPO shall have a written policy established with (a) laboratory(s) approved by the American Society for Histocompatibility and Immunogenetics (ASHI) or the OPTN. This policy should be determined by the specimen requirements of the typing laboratory and the quality assurance criteria of ASHI or the OPTN. The policy shall include specific descriptions of the type of specimen, and medium, in addition to the shipping requirements of same.

5.2 STANDARD LABELING SPECIFICATIONS. The Host OPO or the Transplant Center, as applicable, shall be responsible for ensuring that the outermost surface of the transport box containing organs and/or tissue typing specimen containers must have a completed standardized external organ container label (provided by the OPTN contractor). Any previous labels on the transport container must be removed prior to labeling the box so that only one label exists. The OPO shall label each specimen within the package in accordance with policy. The Host OPO is responsible for ensuring that each tissue or donor organ container that travels outside the recovery facility is labeled appropriately.

In the case of deceased or live donor organs that remain in the same operating room suite as the intended candidate(s), the Host OPO (if applicable) and Transplant Center must develop, implement, and comply with a procedure to ensure identification of the correct donor organ for the correct recipient. The Transplant Center must document that the correct organ was identified for the correct candidate prior to transplant. Some type of donor organ labeling and documentation must be present in the candidate chart. A "time out" prior to leaving the donor operating room and an additional "time out" upon arrival in the candidate operating room is recommended. Exception: In the case of a single donor organ/organ segment remaining in the same operating room suite as a single intended candidate for a simultaneous transplant, donor organ labeling and "time outs" are not necessary.

In the case of live donor organs that travel outside the recovery facility, the Transplant Center(s) involved shall be responsible for ensuring that packaging is consistent with the requirements of OPTN Policies 5.2.1 and 5.2.3, and that the outermost surface of the transport box containing the organ must have a completed OPTN/UNOS standardized external organ container label (provided by UNOS). The recovering Transplant Center shall label each specimen within the package in accordance with OPTN/UNOS policy. The recovering Transplant Center is responsible for ensuring that each container that travels outside the recovery facility is labeled appropriately.

5.2.1 The Host OPO or the Transplant Center, as applicable is responsible for ensuring that the Donor I.D. number, donor ABO type, and a secure label identifying the specific contents (e.g., liver, right kidney, heart) are attached to the outer bag or rigid container housing the donor organ prior to transport.

5.2.2 Each separate specimen container of tissue typing material must have a secure label with the Donor I.D. Number, donor ABO type, date and time the sample was procured and the type of tissue. The Host OPO or the Transplant Center, as applicable is responsible for labeling the materials appropriately.

5.2.3 The Host OPO or the Transplant Center, as applicable is responsible for fixing to the transport container the standardized label completed with the Donor I.D. Number, Donor ABO type, a description of the specific contents of the box, the sender's name and telephone number, and the Organ Center telephone number. A transport container is defined as a corrugated, wax coated disposable box, cooler, or mechanical preservation cassette or machine.

5.3 DOCUMENTATION. ABO results must be provided by the Host OPO or the Transplant Center, as applicable in all circumstances during which a donor organ is transported. Properly packaged paperwork containing complete donor information, as described in Policy 2.5.7.1, will be included with the organ transport container in all instances in which the organ is transported.

5.4 PACKAGING. In all circumstances during which donor organ is transported outside the recovery facility, the Host OPO or the Transplant Center, as applicable is responsible for packaging, labeling, and handling the organ in a manner which ensures arrival without compromise to the organ(s). Proper insulation and temperature controlled packaging including adequate ice or refrigeration shall be used to protect the organs during transport. All packaged organs, using disposable transport boxes, must have a red plastic bio-hazard bag that is water tight secured to allow for safe handling by medical and non-medical personnel during transport. This red bag may be placed between the waxed cardboard box and the insulated material holding the wet ice and the organ.

All organs that have been packaged on the donor's back table must be handled using universal precautions. The packaged organs from the donor's surgical back table are to be placed directly into the wet iced shipping container.

5.5 STANDARD ORGAN PACKAGE SPECIFICATIONS. The re-use of disposable transport boxes is prohibited. If the deceased donor organ is to be commercially shipped, such as with a courier service, commercial airline or charter service, the deceased donor organ must be packaged in a disposable transport box. Coolers are permitted for non-commercial transporting when the organ recovery team is taking the deceased donor organ with them from the donor hospital to the candidate transplant center. The re-use of coolers is permitted. All labels for the previous donor organ must be removed before re-using the cooler. The standard package used by members must have the following properties:

5.5.1 A corrugated, wax coated outer container of 200 pound burst strength, or one of equal or greater strength and moisture resistance, must be used.

5.5.2 Inside the moisture resistant outer-container, 1-1/2" thick expanded polystyrene insulated container or its R-factor equivalent must be used. A closed red plastic bio-hazard bag must be placed between the outer container and the polystyrene insulated container to encase the ice.

5.5.3 A closed plastic liner must also be placed inside the polystyrene container to encase the ice. Inside the insulated container, the organ must be protected by a triple sterile barrier and one rigid container which, if sterile, may be considered one of the triple barriers.

5.5.3.1 The rigid container is not required for livers or lungs.

5.5.4 The tissue typing specimen containers must be in a leak proof plastic bag and must not be imbedded in the ice.

5.5.5 The deceased donor paperwork must be in a watertight container. It may be placed in a location specifically designed for the paperwork or inside the outer container, outside of the insulated container.

5.5.6 Accompanying each deceased organ and tissue typing material, a "red top" tube of blood, specifically for confirmation of ABO must be sent to the receiving OPO or transplant center. This tube must be labeled as described in Policy 5.2.2 and placed within the

insulated container. The Host OPO is responsible for ensuring that the tube is appropriately labeled.

5.6 TRANSPORTATION RESPONSIBILITY. The Host OPO, as defined in Policy 2.1, is responsible for transportation of deceased donor kidney(s) and tissue typing material to the primary destination designated by the recipient member, (e.g., laboratory, transplant hospital, or OPO). In charter aircraft situations, before the Organ Center will arrange for this mode of transportation, the Host OPO must agree to use a charter aircraft, and it must be determined who will pay for the charter.

5.6.1 Transportation Costs Incurred for Renal Organs. Payment of transportation costs incurred by the OPTN contractor on behalf of a member for a donor kidney that is unconditionally accepted by a member and subsequently forwarded to another member is the responsibility of the member that forwarded the kidney. Payment of transportation costs incurred by the OPTN contractor on behalf of a member for a donor kidney that is conditionally accepted by a member and subsequently forwarded to another member is the responsibility of the Host OPO.

5.6.2 Transportation Costs Incurred for Tissue Typing Material. Payment of transportation costs incurred by the OPTN contractor on behalf of a member for tissue typing material sent to crossmatch backup recipients for a donor organ that is conditionally accepted by a member is the responsibility of the member which requested backup for the organ.

5.6.3 Transportation Costs Incurred for Non-Renal Organs. Payment of non-renal donor organ transportation costs incurred by the OPTN contractor on behalf of a member is the responsibility of the member that accepts the organ. Payment of transportation costs incurred by the OPTN contractor on behalf of a member for donor organs that have been accepted and transported, but cannot be utilized for transplantation, also is the responsibility of the member that accepted the organ. If a donor organ is first accepted by one member and subsequently forwarded to another member, payment of transportation costs incurred by UNOS on behalf of a member in forwarding the organ is the responsibility of the member that finally accepts the organ.

5.7 VESSEL RECOVERY, STORAGE, and TRANSPLANT

5.7.1 The practice of vessel recovery and immediate use in a solid organ transplant (for example either a current liver or pancreas transplant) should not be disrupted.

5.7.2 The sanction for vessel recovery and storage for use in a subsequent solid organ transplant from a different donor must be sustained: (for example, when the vessels and the liver or pancreas allograft are being transplanted from different donors with different numbers). The vessels cannot be used other than for the implantation or modification of a solid organ transplant.

5.7.3 Vessels can be shared amongst transplant programs. If sharing occurs between transplant programs, the implanting program must write a detailed explanation justifying the sharing and that justification will be reviewed by the Membership and Professional Standards Committee (MPSC). It is the responsibility of the implanting transplant program to notify the OPO and the OPTN of subsequent disposition of the vessels.

5.7.4 If the vessels are stored and subsequently used for the intended recipient or another transplant recipient, the OPO and the OPTN must be notified.

5.7.5 The consent forms used by the recovering OPO must include language that indicates that vessels will be used for transplant.

5.7.6 If the vessels are being stored, the procedure of packaging, labeling, storage, the medium and temperature, the location, and the duration of storage must be addressed by the organ transplant community using the following standards.

5.7.6.1 The vessels must be stored in a Food and Drug Administration (FDA) approved preservation solution (ex. UW, Custodial HTK).

5.7.6.2. The vessels must be stored in a sealed container labeled with the recovery date, ABO, serology, container contents, and the Donor ID Number for tracking. The appropriate packaging of the vessel should be completed in the donor operating room. Label should clearly state for use in organ transplantation only.

5.7.6.3 The vessels must be stored in a secured refrigerator within a range of 2 to 8 °C.

5.7.6.4 The vessels can be stored up to a maximum of 14 days from the original recovery date.

5.7.6.5 The Transplant Center must designate a person to monitor and maintain records, destroy, and notify the OPO and OPTN of outcome and/or use of vessels. This designated person would maintain information on all donor vessels including monitoring and maintaining all records relating to the use and management of donor vessels (i.e. subsequent positive serology testing, monitor inventory of stored vascular conduits, monitor the refrigerator, ensure records are up to date and available with the conduits, destroy the vessel when expired, and notify the OPO of its use or disposal).

5.7.6.6 The transplant surgeon must be provided around the clock access to the donor information for his/her review prior to using the donor vessel in a recipient other than the intended recipient.

5.7.6.7 There must be daily monitoring of the vessels with documented security and temperature checks by the transplant center.

5.7.6.8 A log of stored vessels must be maintained by the transplant center at the point of storage.

5.7.7 If vascular conduits from donors with positive serology for hepatitis are subsequently used in other than the intended recipient, the implanting transplant center must provide a detailed explanation for the use of this conduit for review by the MPSC.